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10/776,470	02/11/2004	William J. McBride	329532	3576

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FAEGRE & BENSON LLP
PATENT DOCKETING
2200 WELLS FARGO CENTER
90 SOUTH SEVENTH STREET
MINNEAPOLIS, MN 55402-3901

EXAMINER

LAO, MARIALOUISA

ART UNIT	PAPER NUMBER
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1621

MAIL DATE	DELIVERY MODE
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11/08/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/776,470

Applicant(s)

MCBRIDE ET AL.

Examiner

M. Louisa Lao

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-135 is/are pending in the application.
- 4a) Of the above claim(s) 1-106 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 107-114, 116-130 and 132 is/are rejected.
- 7) ☒ Claim(s) 115, 129 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/04/2006 04/13/2007.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group III (claims 107-130 and 132) in the reply filed on 10/19/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-106 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/19/07.

Claim Objections

3. Claim 129 is objected to because of the following informalities: In line 10, the claim recites "N-alklyated", where it may have intended "N-alkylated". Appropriate correction is required. Further, Applicants are requested to ascertain and check the specification for typographical and grammatical errors.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent. -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 107, 108, 110, 111, 113, 114, 116, 119, 120-125, 129, 130 and 132 are rejected under 35 U.S.C. 102(a) & 102(b) as being anticipated by Platzek et al. (WO97/25305 *equivalent to* US6080785, US'785).
6. The instant claims are drawn to a method of preparing a polyalkylene polyamine, comprising *inter alia* reacting in a first reaction solution a polyalkylene polyamine having an amine terminus with a molecule comprising a protecting group to form a polyalkylene polyamine with a protecting group attached predominantly to a single amine terminus; reacting in a second reaction solution the polyalkylene polyamine extracted from the first reaction with an alkylating agent to form an N-alkylated polyalkylene polyamine with a protecting group attached predominantly to a single amine terminus; extracting said N-alkylated polyalkylene polyamine; removing the protecting group and reacting said N-alkylated polyalkylene polyamine with a second agent to form an N-alkylated polyalkylene polyamine.
7. US'785 teaches new derivatives of ethylenediaminetetraacetic acid (EDTA); diethylenetriaminepentaacetic acid (DTPA) or triethylenetetraaminehexaacetic acid (TTHA) or compounds of the general formula (column 2 lines 8-27 and lines 39-59). US'785 teaches the synthesis of preparing polyalkylene polyamine by the reaction of a substituted amine initially with halogenated compound, which carries a protecting group and the subsequent cleavage of the protecting group allowing a directed chemoselectivity for the site to have the desired functional attachment.
8. US'785 further typifies this process by working examples in columns 4 to 11.
9. The cited prior art reference anticipates the instant claims since the reactions are drawn to the same general scheme of making polyalkylene polyamines.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

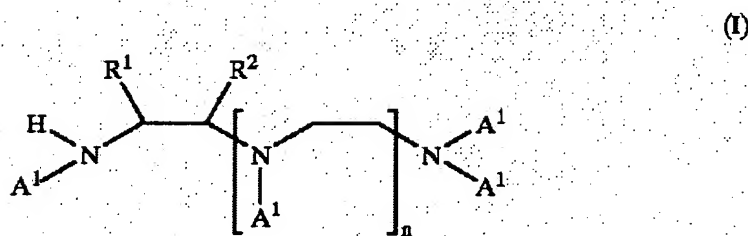
13. Claims 107-130 and 132 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platzek et al. (US6080785, US'785) and Platzek et al. (US5676923, US'923).

14. The instant claims are drawn to a method of preparing a polyalkylene polyamine, comprising *inter alia* reacting in a first reaction solution a polyalkylene polyamine having an

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amine terminus with a molecule comprising a protecting group to form a polyalkylene polyamine with a protecting group attached predominantly to a single amine terminus; reacting in a second reaction solution the polyalkylene polyamine extracted from the first reaction with an alkylating agent to form an N-alkylated polyalkylene polyamine with a protecting group attached predominantly to a single amine terminus; extracting said N-alkylated polyalkylene polyamine; removing the protecting group and reacting said N-alkylated polyalkylene polyamine with a second agent to form an N-alkylated polyalkylene polyamine.

15. US'785 teaches new derivatives of ethylenediaminetetraacetic acid (EDTA); diethylenetriaminepentaacetic acid (DTPA) or triethylenetetraaminehexaacetic acid (TTHA) or compounds of the general formula (column 2 lines 8-27 and lines 39-59), as shown:



in which

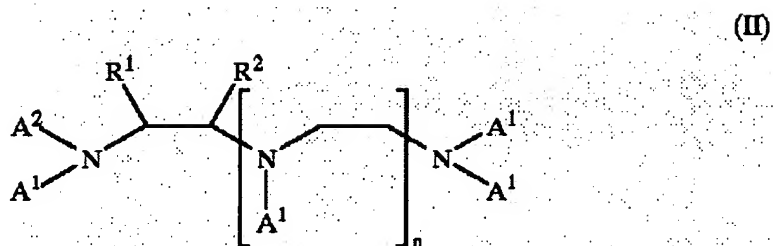
n stands for numerical values 0, 1 or 2,

A^1 stands for radical $-\text{CH}_2\text{CO}_2^+\text{Bu}$,

R^1 and R^2 either in each case stand for hydrogen or together stand for $-(\text{CH}_2)_m-$, in which m can assume numerical values 3 to 6, provided that R^1 and R^2 only then together stand for $-(\text{CH}_2)_m-$, if n stands for value 0.

and

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in which

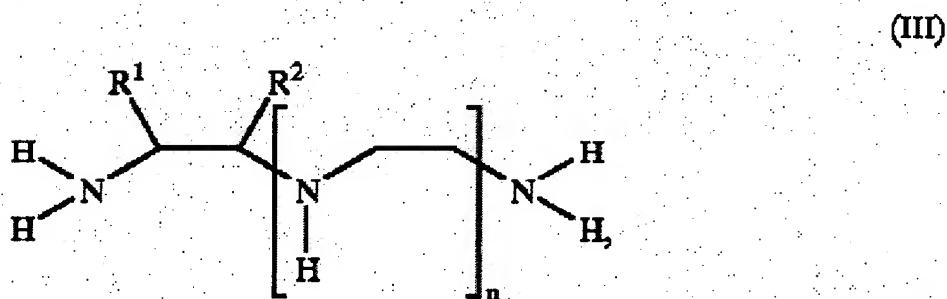
n stands for numerical values 0, 1 or 2,

 A^1 stands for radical $-\text{CH}_2\text{CO}_2^t\text{Bu}$, A^2 stands for radical $-\text{CH}_2\text{CO}_2\text{H}$,

R^1 and R^2 either in each case stand for hydrogen or together stand for $-(\text{CH}_2)_m-$, in which m can assume numerical values 3 to 6, provided that R^1 and R^2 only then together stand for $-(\text{CH}_2)_m-$, if n stands for value 0.

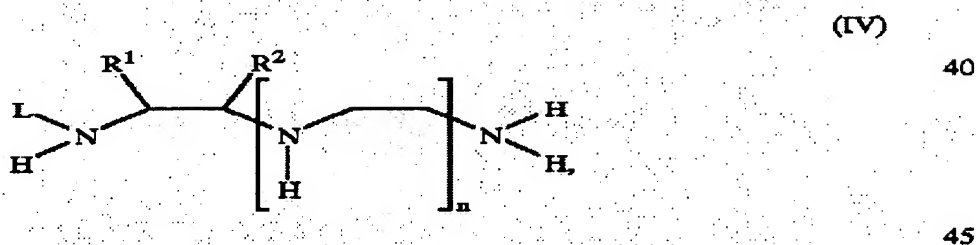
16. US'785 teaches the process for the production of said compounds of general formula (I):

characterized in that a compound of general formula III

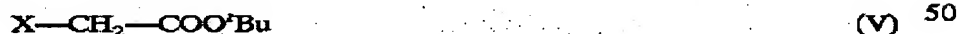


in which R^1 , R^2 and n have the above-mentioned meanings, is reacted with a protective group reagent to a compound of

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general formula IV

in which R^1 , R^2 and n have the above-mentioned meanings, and L stands for a trifluoroacetyl group or a benzyl group, the latter is reacted with compounds of general formula V



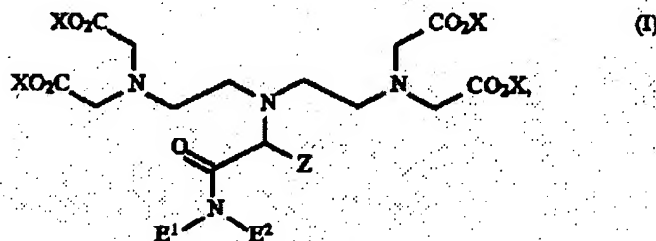
in which X stands for chlorine, bromine or iodine, and the thus obtained compound is converted into the compound of general formula I by cleaving protective group L .

After the protective group L is cleaved off by alcoholic ammonolysis of the trifluoroacetyl group or by catalytic hydrogenation (H_2 , Pd) of the benzyl group, the desired compound of general formula I is obtained directly (column 3 lines 5-67).

17. US'785 further typifies this process by working examples in columns 4 to 11.

18. The instant claims differ from the US'785 in that not all of the Applicants' reactants are exemplified, for example the protecting group, Z , of structure recited in claim 112; or Applicants' starting materials.

19. US'923 teaches substituted diethylenetriaminepentaacetic acid monoamide derivatives, of the general formula, with substituents described therein (column 2 lines 10-60):



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20. US'923 teaches the formation of carboxylated polyalkylene polyamines (column 7 lines 66-67 bridging to column 8 lines 1-18). US'923 teaches that the hydrogenolytic cleavage of benzyl derivatives takes place with the use of palladium catalysts (column 8 lines 43-48). US'923 teaches further the formation of carboxylated polyalkylene polyamines (column 8 lines 53-67 bridging to column 9 lines 1-67).

21. The instant claims differ from the cited prior art references (US'785 and US'923) in that the instantly claimed process exemplifies other starting materials in the general scheme of preparing polyalkylene polyamines, which in light of the anticipating examples would render the utilization of alternative materials obvious.

22. The difference is unpatentable; since at the time of Applicants' invention, it would have been *prima facie* obvious to one of ordinary skill in the art to recognize that the process of chemical modification of a functional group in amines with the introduction of protecting groups to effectuate chemoselectivity in a chemical reaction as a known practice, particularly in a multi-step organic synthesis as taught in US'785 and US'923. As in the instantly claimed process, making additional compounds generically disclosed by the cited prior art reference especially in view of the anticipating compound noted above, and to expect to produce further compounds useful for diagnostic uses.

23. An artisan would be motivated to use alternate starting materials, which are equivalent, as dictated by cost and availability, to effectuate a multi-step organic synthesis reaction using protecting groups with a reasonable expectation that chemically equivalent alternatives would be useful in providing chemical selectivity.

The use of different, but analogous reactants in an old process does not render the process itself unobvious. *In re Durden et al.* 226 U.S.P.Q. 359.

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The Supreme Court in *KSR* noted that if the actual application of the technique would have been beyond the skill of one of ordinary skill in the art, then the resulting invention would not have been obvious because one of ordinary skill could not have been expected to achieve it.

Allowable Subject Matter

24. Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MLouisa Lao whose telephone number is 571-272-9930. The examiner can normally be reached on Mondays to Thursdays from 8:00am to 8:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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